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National
COMMUNITY
PHARMACISTS
Association

Formerly NARD, the National Association of Retail Druggists

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June 1, 1999

Dockets Management Branch
Food and Drug Administration
(HFA-305), Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: FDA proposed draft federal/state memorandum of understanding (MOU)
on interstate distribution of compounded drug products
Docket No.: 98N-1265

To Whom It May Concern:

The purpose of this comment is to respond to the cited proposed draft MOU (See 64 Fed.Reg.3301 (1-21-99). The National Community Pharmacists Association (NCPA) represents the professional and proprietary interests of independently owned pharmacies and the thousands of pharmacists that practice in independent pharmacy settings. Our members function in the market in a variety of forms. They do business as single stores ranging from apothecaries to full line high volume pharmacies; as independent chains (e.g., 100 pharmacies) and as franchisees such as NCPA members involved with the Medicine Shoppe franchise. Whatever the form of business entity, however, independent pharmacists are the decision makers for this wide variety of NCPA member companies.

The NCPA was intimately involved with the legislative and political process which led to the enactment of section 127 of the FDA Modernization Act of 1997 and its' section 503A(b)(3)(B) which contemplated in the alternative that states enter into a MOU "with FDA that addresses the interstate distribution of inordinate amounts of compounded drug products and provides for investigation by State agency of complaints related to compounded drug products distributed outside such State". The FDA was directed to develop a standard MOU for use by states "in consultation with" the National Association of Boards of Pharmacy (NABP).

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Unfortunately the proposed FDA draft, which Congress intended to be used as guidance by the states has been converted into a series of unauthorized dictates. Particularly obnoxious are the draft MOU's provisions that emasculate states exclusive constitutional authority to regulate the practice of pharmacy. Such provisions include an arbitrary limit on the percent of compounded prescriptions that can be delivered interstate and a litany of mandates to the states directing what should be investigated and how investigations are to be conducted.

This wrong headed takeover scheme flies in the face of clear congressional intent to defer to the states while developing a cooperative framework between the FDA and the states regarding complaints about compounded drug products sent across state lines.

In addition to the myriad of unauthorized federal intrusions, the proposed draft needs to be clarified to indicate that a physicians signature on a valid prescription indicates that a physician has determined that the medication is necessary for the identified patient.

The FDA proposed draft should be withdrawn. The FDA should actually consult with NABP in a manner that will foster the atmosphere of cooperation between the FDA and the states that the Congress intended.

Furthermore, is the intention of the NCPA to be associated with the comments on this same docket numbers submitted by the International Academy of Compounding Pharmacists and by the Women's International Pharmacy .

Sincerely,

John M Rector

John M. Rector
Sr. Vice President for
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Pages including cover sheet: 3

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98N-1265

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